PRESSURE SENSOR FOR THERAPEUTIC DELIVERY DEVICE AND METHOD

Cross-Reference To Related Applications

[0001] This application is a continuation of Application No. 10/347,567, filed January 17, 2003, which is a continuation of Application No. 09/816,708, filed March 23, 2001, which claims the benefit of Provisional Application No. 60/191,610, filed March 23, 2000, the disclosure of each of which is incorporated in their entirety herein by reference.

Field Of The Invention

[0002] The present invention relates to an apparatus and method for affecting a body tissue, such as the heart, at the tissue surface, for purposes of injecting material into the tissue or otherwise stimulating a desired therapeutic effect on the tissue.

Background Of The Invention

[0003] Percutaneous catheter-based treatments of cardiovascular disease require that navigation of the catheter within the body be done with a mode of visualizing the catheter as it is moved within the body. The most popular mode of visualization is X-ray fluoroscopy, where an operator is able to monitor a radiopaque device as it travels within a body lumen, such as the cardiovascular system.

[0004] Recently, interventional procedures that require catheter navigation within the chambers of the heart have been developed; these include electrophysiological mapping and ablation and transmyocardial revascularization. These procedures also often require that the tip of the catheter be placed in contact with a wall of the beating heart in order to deliver the desired treatment safely. Potential complications of this procedure may be perforation of the wall when excessive force is applied or ineffective treatment due to poor tip contact. Under fluoroscopic guidance it is often difficult to assess when the catheter tip has reached the wall because live fluoroscopy does not visualize that wall itself, since it is not radiopaque. For the same reason, even after the catheter tip has reached the wall, it is difficult to determine whether the tip consistently remains in contact with the wall or if excessive force is applied to the wall. Finally, it is also difficult to determine whether the catheter tip is substantially perpendicular to the wall because fluoroscopy yields a two-dimensional image of the device in three-dimensional space.

[0005] Thus, for procedures where a medical instrument must be placed in firm but not excessive contact with an anatomical surface, there is an apparent need for a device which is able to provide information to the user of the instrument that is indicative of the existence and magnitude of the contact force. Furthermore, for procedures where the medical instrument must also be placed either perpendicular or at some selected angle to the anatomical surface, there is an apparent need for a device which is able to provide information to the user of the instrument that is indicative of the incident angle of the contact force with respect to the anatomical surface.

Summary Of The Invention

[0006] It is therefore an object of this invention to provide such a device for overcoming one or more of the above-mentioned problems.

[0007] It is another object of this invention to provide information to the user of a medical instrument, such as a catheter, that must be placed in contact with the surface of an anatomical structure, to increase the likelihood of safely delivering the desired treatment while reducing the possibility of inflicting perforation type injuries or providing inadequate treatment.

[0008] It is further an object of this invention to provide a method for generating information regarding whether the tip of a medical instrument, such as a catheter or probe, is in contact with a surface of a tissue or organ, and, if so, the magnitude of the contact force and the incident angle of the contact force with respect to the anatomical surface.

[0009] In summary, the present invention is an apparatus for treating a selected patient tissue or organ region, at the surface of such region. The apparatus may have an accessing tool for accessing the patient region, the accessing tool having a distal end, and a proximal end at which the tool can be manipulated to place the distal end adjacent to the patient region.

[0010] The apparatus may also have a probe carried on the distal end and defining a contact surface that may be urged against the patient region thereby creating contact pressure. The apparatus may further have at least one pressure transducer, wherein each pressure transducer may be operatively coupled to the probe and capable of producing a measurable response to the contact pressure experienced adjacent to the pressure transducer. A monitoring device may be operatively connected to each pressure transducer, for determining contact pressure. At least one effector may be provided, wherein each effector may be operatively disposed on the probe for producing a given effect on the patient region

when the effector is activated. An activator may further be provided, which may be operatively connected to the effector, and by which the effector can be activated.

Brief Description Of The Figures

[0011] Fig. 1 illustrates the force contact transducer attached to a probing tool and monitoring circuitry;

[0012] Fig. 2 is an exploded view of a force contact transducer constructed in accordance with embodiments of the invention;

[0013] Fig. 3 illustrates a view of the cap and base of the force contact transducer;

[0014] Fig. 4 illustrates a view of the cap region of the force contact transducer;

[0015] Fig. 5 illustrates a detailed exploded view of contact elements of the invention;

[0016] Fig. 6 illustrates one embodiment of the invention that employs a thin film transducer array disposed around a tool shaft;

[0017] Figs. 7A-7D illustrate embodiments of a transducer array and a single transducer;

[0018] Fig. 8 illustrates, in simplified view, the cap region of a transducer capable of detecting both axial and lateral force components applied to the sensor; and

[0019] Fig. 9 illustrates an embodiment of the invention that measures force movement by electrical inductance, rather than by resistance.

Detailed Description Of The Invention

[0020] Fig. 1 shows an apparatus **44** constructed according to the invention. The apparatus provides an assembly or tool **46**, for accessing a patient tissue or organ region **47**, and a sensor device **20**, detailed below, for determining the pressure of the probe against the target tissue and, in some embodiments, the angle of contact between the probe and target tissue.

[0021] In general application, the assembly is used to access an internal target region, and to provide a therapeutic stimulus, such as injection of a therapeutic compound or gene, forming a laser channel, or introducing an injury, *e.g.*, by ultrasonic waves, infrared radiation, or mechanical injury on or below the surface of the target region, *e.g.*, to stimulate an angiogenic response in the target region. The therapeutic stimulus is preferably administered/provided through the assembly probe. The sensor device operates, in accordance with the invention, to provide information to the user about the position of

the probe with respect to the target region, since the target region is generally not directly viewable by the user, *e.g.,* physician.

[0022] In the embodiment shown, the medical instrument includes a rigid shaft **46**, which may have a curved section, as shown in Fig. 1. Alternatively, the medical instrument is a flexible catheter, *e.g.,* for delivery of a therapeutic stimulus to a target site within the vasculature or heart. The distal end of the shaft may be the base of the transducer, as shown in Fig. 1, or a separate element securely affixed to the base. A handle **48** is attached to the proximal end of the shaft or base. In one embodiment, the shaft is pivotally attached to the transducer base to permit the tip of the medical instrument to bend. The handle may include a control panel **50** for control of the instrument by the user. Also shown are a bridge divider, an output device **54**, such as a display device, and signal processing circuitry **56** whose operation is described below.

[0023] While not detailed here, handle **48** may be designed to produce a selected therapeutic effect on target tissue, when a desired pressure and/or pressure contact angle is sensed between the probe and target tissue. The therapeutic effect may be, for example, the injection, by a needle or needleless injection system, of a solution or suspension of a therapeutic compound or gene, or a radiation or ultrasound injury produced by a light-carrying fiber or sonic device on the probe, or a mechanical injury produced by a mechanical tool on the probe. The apparatus may therefore be equipped, according to well-known devices, to provide an extendable needle, a light fiber, an extendable mechanical-injury device, or the like to produce the desired therapeutic effect, in response to a signal applied by the user to handle **48**. That is, handle **48** may include structure for activating the therapeutic receptor at the distal end of the apparatus. In one embodiment, the therapeutic response is activated when the distal end of the apparatus is positioned against the target tissue with a desired pressure, that is, above a selected pressure threshold or within a desired pressure range, as determined from the pressure sensor device of the invention. In addition, angle of contact as sensed by the device may be employed as a variable to be considered in an automated triggering.

[0024] Fig. 2 is an exploded view of a force contact transducer or device 20 constructed in accordance with embodiments of the invention. Device **20** includes an elongate, cylindrical base **22** that may be constructed of non-conductive material such as polycarbonate or a metallic conductive material such as surgical steel or similar material. The base has a larger diameter portion **24** that may serve as, or be attached to, a shaft of an associated medical instrument, such as a needle-delivery device or light fiber, in which the

transducer is incorporated. Extending from the distal end of the larger diameter portion is a reduced diameter portion **26** (*i.e.,* a reduced diameter shaft).

[0025] Attached to, or formed integrally with, the reduced diameter portion is a flange **28** that has a central opening **28a** and one or more notches, such as notch **28c,** formed in its outer edge. An upper surface **28b** of the flange is electrically conductive (by placement of a not shown conductive layer and serves as one of the electrical conductors of the transducer. The details of the base are illustrated in Fig. 4.

[0026] Device **20** further includes a cap **30**, which is generally cylindrical in shape and has an axial bore extending therethrough to define an inner wall. A plurality of rectangular feet **30b** are formed on one end surface **30c** of the cap, which surface acts as the second electrical conductor of the transducer. The cap is shown in more detail in Fig. 4.

[0027] Sandwiched between conducting surfaces **30c** and **28b** are: (i) a conductive or semi-conductive elastomer **32** that is preferably made of carbon loaded silicone rubber or other material with similar characteristics, and (ii) a thin, non-conducting insulating layer **34** that is preferably made of mylar, polyimide or other material which exhibits similar insulating or dielectric properties. Each of these components **32** and **34** has an opening **32a** and **34a** respectively formed therein so that these components may be received on the reduced diameter portion **26** of base **22**. A lower surface of the insulating layer abuts against, but does not completely cover, conductor surface **28b**, so that a lower surface **32b** of the conductive elastomer is able to selectively make contact with conductor surface **28b** based on a force applied to the transducer, as will be explained in more detail below.

[0028] In the illustrated embodiment, this is accomplished by making opening **34b** in the form of a slot, as seen best in Fig. 5. However, this is merely one example; other arrangements are possible. For example, the insulator may have a central opening and a plurality of radial arms providing a plurality of circumferential slots through which electrical contact may be selectively made between the elastomer and the confronting conductive surface **28b** of flange **28**.

[0029] Formed along the outer edge of insulator **34** is a notch **34c**, which is aligned with notch **32c** in elastomer **32** and slot **28c** in flange **28**, as seen particularly in Figs. 3 and 4. The notches accommodate a pair of electrical leads **36a** and **36b** that are in electrical contact with conducting surfaces **28b** and **30c**, respectively, as shown in Figs. 3 and 4.

[0030] Formed in an upper surface of the conductive elastomer is a plurality of indents or footprints that correspond to the feet **30b** formed on conductive surface **30c** of the cap. Each one of the feet **30b** is adapted to fit securely within its complementary

footprint to maintain constant contact between the conductive surface of cap **30** and the upper surface of conductive elastomer **32**.

[0031] It is desirable to seal the components of the contact force transducer apparatus to prevent ingress of bodily or other fluids into the electrical regions of the apparatus. Furthermore, it is highly desired to seal the invention to prevent the egress of components from the contact force transducer apparatus. Accordingly, one skilled in the art would realize that numerous means for sealing the apparatus are possible. For example, a potting material may be introduced at component junctions so as to seal the device without interfering with its intended function. Alternatively and as discussed in detail below, a shroud or tip may be employed to seal the apparatus. Such sealing means may be preformed or formed in place, for example, by dipping an appropriately masked apparatus in a sealing compound to create a tip or shroud in place.

[0032] A tip element **38** may be employed to protect the cap. In one embodiment, the tip has a lower end **38a** that is securely attached to an upper end of the cap, as shown in Fig. 2. In another embodiment, the tip extends over the cap-conductive elastomer-insulator assembly (not shown). In either case, when the tip is used, its outer surface **38b** acts as the contact surface of the transducer. When the tip is not employed, the upper end of the cap is the contact surface. The transducer components including the tip in assembled form are shown in Fig. 2. When the tip is not used, upper end **30d** serves as the contact surface of the transducer. The assembled transducer excluding the tip is shown in Fig. 3.

[0033] If desired, a suitable biologically compatible coating or cover **40** may be applied to the cap-conductive elastomer-insulator-flange assembly (and tip if included) to protect it and to prevent fluid ingress. Such a cover or coating, with portions broken away, is shown in Fig. 2.

[0034] A second embodiment of the invention (not shown) is similar to the first except that it further includes a thin insulator which fits between cap **30** and tip **38** to reduce the friction between these components and enable them to move relative to each other as the force applied to the contact surface of the transducer is varied.

[0035] In operation, an electrical excitation signal is generated in a bridge or divider circuit **52** (Fig. 1) and applied to the conductive surfaces or other electrical elements of the sensor described below. If a force below a predetermined threshold is applied to the contact surface of the transducer, the excitation signal will remain the same. However, if the applied force is just above the predetermined threshold, conductive elastomer **32,** which is in constant contact with conductive surface **30c**, will extend or be pushed through the openings or perforations in insulating layer **34** to make contact with conductive surface **28b.**

This causes the impedance between the two conductive surfaces to decrease, producing a change in the excitation signal which indicates that minimum contact has been made. As the applied force is further increased, the conductive elastomer compresses causing a further proportional drop in the impedance that, in turn, produces corresponding change in the excitation signal. Thus, the impedance and therefore the excitation signal varies with the magnitude of the applied force.

[0036] The bridge/divider circuit is in electrical communication with an output device **54** which may be in the form of an audio or visual device adapted to provide an information signal to the user indicative of whether the outer surface of the transducer has made contact, and, if so, the magnitude of the contact. The output device may take a variety of different forms. For example, an LED bar graph or other display capable of rendering a graphical or visual representation may be used to provide a continuous, quasi-continuous or discrete indication of the magnitude of a force applied to the contact surface of the transducer, from a minimum applied force indicative of minimum contact to a predetermined maximum. Alternatively, or in addition, a speaker or other audio device may be used to emit a sound when minimum contact is made and to emit proportionally louder sounds as the firmness of the contact increases.

[0037] The sensitivity of the excitation signal and hence the information signal may be adjusted in a number of different ways. One way is by using an elastomer with a different conductivity and/or compressibility. Another way is with electronic signal processing circuitry with adjustable amplification and filtering. Such a signal processing circuit **(56)** may be physically integrated with the bridge/divider circuit, or may be a separate circuit that is in electrical communication with the bridge/divider circuit, as illustrated in Fig. 1. The sensitivity of the signals (excitation and information) may also be adjusted by varying the size of the openings or perforations in the insulating layer, or by varying the thickness of the insulating layer. Larger perforations increase the sensitivity. In any case, the sensitivity of the transducer is set based on the desired contact force threshold and the minimum magnitude of change to be detected.

[0038] A flat transducer contact surface will generate less of an output signal if the tip is in contact with tissue surface at an oblique angle. On the other hand, a rounded or tapered contact surface will generate a greater output signal at an oblique angle of contact. Thus, the geometry of the contact surface may be tailored to provide feedback about the perpendicularity of the contact between the medical instrument tip and the tissue surface. Optionally, the friction coefficient of the tip or exposed cap material at the contact surface may be altered to provide for shear force as the probe is situated upon a tissue surface in a

way that a lateral force vector component manifests, assuming at least some of the thrust force applied creates a lateral force component. The less the friction between the contact surface and the tissue surface, the less the shear or lateral force component realized.

[0039] In another embodiment, a plurality of discrete transducers can be distributed on the tip of a medical instrument to provide further information regarding the perpendicularity of the contact. In the case of two transducers, each covers 180 degrees of the tip surface; in the case of three transducers, each covers 120 degrees, etc. The combined signal from the multiple transducers may be processed to provide, in addition to contact and magnitude information, angle of contact of information as well.

[0040] In another particularly preferred embodiment, a transducer, or transducers if contact angle sensing is sought, may comprise a thin double mylar film layered sandwich as described in Krivopal, U.S. Patent 5,989,700, herein incorporated in its entirety by reference. Looking at Fig. 6, the instant invention differs from Krivopal in that sensor **60** has sensor elements **68** on a support **70** having an aperture **76** disposed in the center to permit tool shaft **64** to be disposed at a normal angle through the sensor or sensor array. Each individual sensor area is electrically accessible by leads **66**.

[0041] The sensor support **70** can either be rigid or elastic depending on the degree of flexibility sought in the device. Disposed above the sensor support is a resilient or elastomeric cap **72** which mechanically communicates the probe tip contact surface incident angle and total contact force downward to sensor **60**. Cap **72** may further include protuberances **78** to focus the communicated force onto sensors **68**.

[0042] The entire probe tip may be covered by a sheath, not shown. Alternatively, a transducer, such as a thin film transducer, may be positioned directly on the contact surface, thereby creating a superior contact surface. Alternatively, the probe may lack a cap element and thus directly expose a transducer, such as a thin film transducer, to a tip surface opposite the tip contact surface, or the transducer may itself comprise the tip surface, and thus the contact surface as well. Each of these embodiments just described may include one or more transducers so that incident angle as well as force may be detected.

[0043] Considering now the embodiments shown in Figs. 7A-7D, a sandwich **112** has a top mylar film **112a** (*i.e.,* a primary layer of material), an upper conductive ink layer **112b** applied to the lower surface region of the top mylar film **112a**, an upper semiconductive ink layer **112c** applied to the upper conductive ink layer **112b**, an air gap **112d**, a lower semiconductive ink layer **112e** disposed upon a lower conductive ink layer **112f** which is disposed on the upper surface of a bottom mylar film **112g** (*i.e.,* a secondary layer of material).

[0044] There may be an insulating ring or sections surrounding the above described ink sandwich to separate the upper mylar layer from the lower mylar layer thus creating the air-gap between the upper and lower semi-conductive ink layers. In the case of a multiple transducer array **100**, several sandwich regions **102, 104, 106** may be arranged upon the plane created by the mylar film, each region being in electrical communication with the monitoring unit, and each region is independently responsive to the contact force present at the corresponding region of the contact surface of the probe thus providing a means of determining the incident angle of the contact force with respect to the tissue surface by comparing the individual responses of each transducer sandwich region.

[0045] Alternatively, each sandwich region **114** may be a separate mylar film sandwich **116**, with each electrode **118, 120** individually in electrical communication with the monitor device.

[0046] In another embodiment, the pressure transducers may be a combination of a purely mechanical resilient device such as an elastomeric spacer, and a mechanical or electrical device for measuring the effect of the force upon the resilient device. Measurement may include a mechanical deflection of mechanically communicated information to a portion of the tool distal from the patient surface, or may be a switch or potentiometer mechanically operating above its inherent mechanical (frictional) resistance. Mechanically communicated deflection may be monitored and displayed to a user as described below.

[0047] Fig. 8 shows another embodiment of a sensor device **80** for use in the apparatus of the invention. The device shown here is designed to measure both axial pressure, along an axis normal to the contact face of the probe, and lateral direction, *i.e.*, force applied to a side region of the probe. The device includes a rigid mechanical support **81** which is attached at its lower end in the figure to the distal end of the accessing tool, and which provides a central opening **82** through which the therapeutic effector, *e.g.*, needle or optical fiber is received.

[0048] The device has a flexible cap **83** that is rigidly attached to a radially extending annular ring **91** in the support. The cap is formed of a flexible polymer or elastomer material or other flexible material that permits the cap to deform when pressure is applied to the cap, when the probe is in contact with the target tissue. Carried on an inner, upper surface of the cap is a preferably segmented annular electrode ring **84** positioned to contact an annular conductive elastomer member **86** of the type described above, when an axial pressure acts and distorts the upper surface of the cap. The elastomer member, in turn, is seated on an insulative spacer **85** that provides an electrical barrier between the elastomer

and support, but which provides openings or notches through which the elastomer can be pressed, when an axial force acts on it, as described with reference to Figs. 1-4.

[0049] In operation, when an axial force is applied to the cap, the cap is distorted to bring electrode ring **84** into contact with elastomer member **86**, pushing the elastomer through spaces in the insulative spacer **85**. This changes the resistance of a circuit containing the two electrodes and the elastomer member in proportion to the total contact area that the elastomer makes with the support electrode, and this change in resistance is recorded and displayed to the user.

[0050] Carried on the annular side region of the support is a plurality of insulative members, such as elastomeric members **88a, 88b**, arranged circumferentially about the support. Typically, the device includes three such members, each member being carried on an insulative spacer, such as spacers **89a, 89b.** Similarly, carried on the inner confronting surface of the cap is a segmented electrode **87** which is disposed to make contact with individual elastomer members **88a, 88b** when side regions of the cap are distorted by side pressure and brought against the confronting elastomeric segments. Thus, side-directed pressure is detected, as above, by a change in the resistance in one or more of the side elastomer members, as the cap electrodes push against the elastomer member(s), forcing surface portions of the member(s) through openings in the spacers, and lowering the resistance of each associated circuit containing the affected elements. The user thus has information about axial pressure, from the change in resistance (impedance) in the upper-cap circuit, and information about angle of contact by the extent of asymmetry in measured resistances of the three side circuits.

[0051] In a purely mechanical device there may be disposed between the probe and the proximal end of the tool an elastic resilient support. Absent any surface contact, the probe's contact surface remains perpendicular to the thrust axis of the tool because of the elastic resilient support. Attached to the tool side of the probe are the ends of at least 3 or more flexible shafts running parallel or coherently through the tool length. These shafts run slidably through and protrude beyond lumens within the tool body beginning at the probe facing side of the proximal end of the tool and terminating as openings at the distal or user end of the tool. As the contact surface is deflected away from the thrust axis of the tool, the distance between the probe contact surface and the tool varies depending on the angle of deflection. The shaft, beneath where the distance between the contact surface of the probe and the proximal end of the tool is least, will protrude out more from the distal or user end of the tool, whereas the shafts opposite will recede into the tool at the distal or user end. Consequently, a user will be able to observe angular relation of the probe to the tool by

observing the protrusion or withdrawal of the shafts, thereby the user could adjust the incident angle of the tool to achieve a balanced shaft display. One skilled in the art would readily recognize that many variations of this embodiment are possible, especially with respect to how the angular information is displayed to the user.

[0052] In another, multi-transducer embodiment, each pressure transducer is independently elastically and resiliently related to the contact surface, and another embodiment provides for each pressure transducer being mutually elastically and resiliently related to the contact surface.

[0053] In yet another embodiment, the monitor is operatively connected to the activator such that at a pre-selected measurement, the activator is activated thus causing the effector to activate. In a related embodiment, the monitor is operatively connected to the activator such that the activator can only be manually activated by the user when the monitor measures a predetermined measurement from the pressure transducer. In yet another related embodiment, the monitor does not affect the operability of the activator.

[0054] In yet another embodiment, the pressure transducer may respond to deflection by varying capacitance rather than resistance. Capacitance can be varied by sandwiching a pressure sensitive dielectric material between two electrodes. Alternatively, changes in pressure can be measured by varying inductance with inductor transducer device **90** illustrated in Fig. 9. As seen, the device includes a cap **94** which can move in an axial direction (the direction of arrow **100**) toward and away from the relaxed (no-pressure) position shown in the figure, mounted for such axial movement on a support **92**, which is carried on the distal end of the apparatus tool. The support provides an induction coil **99** formed of conductive wire windings **98** which are positioned adjacent a cylindrical permanent magnet **96** mounted on the cap.

[0055] Movement of the cap in the direction of arrow **100** carries magnet **96** past the inductive wires, producing a change in the inductance of the coil. Such changes can be monitored by incorporating the inductor into a LC or inductor-capacitor oscillating circuit and monitoring the change in the resonant frequency of the LC circuit.

[0056] In yet another embodiment, any transducer described herein may be combined with an ultrasonic transducer capable of detecting tissue density or thickness. For example, the ultrasonic transducer of Zanelli *et al.*, U.S. Patent 6,024,703, herein incorporated in its entirety by reference, discloses an ultrasound device for axial ranging. This would provide for the ability to limit the throw or depth that an effector element is permitted to penetrate into the patient tissue underlying the tissue surface thus avoiding

either too shallow, thus ineffective penetration, or too deep and thus harmful penetration of the effector element.

[0057] As should be apparent from the foregoing description, the present invention, unlike fluoroscopic methods, provides force information such as but not limited to, force contact, magnitude and direction or incident angle with respect to the patient tissue surface, for catheter-based surgical procedures or other medical procedures where the degree of contact between the medical instrument and a surface of an anatomical structure is useful to know. In addition, such information may be provided in real-time and in a variety of formats using a low cost, disposable force contact transducer of the type disclosed herein. Such a transducer may be easily integrated into existing catheter tools, eliminating the need for extensive hardware/software interfaces.

[0058] While various embodiments of the invention have been illustrated and described, it will be evident to those skilled in the art in light of the foregoing disclosure that many further alternatives, modifications and variations are possible. For example, the insulator need not be a separate element but may be in the form of an insulative coating that is selectively applied to the conductive surface of the flange to permit the lower surface of the conductive elastomer to make contact with that conductive surface in accordance with the teachings of the invention. The invention disclosed herein is intended to embrace all such alternatives, modifications, and variations as may fall within the spirit and scope of the appended claims.